PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PRD 0032-PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/10092	International filing date *(day/month/year)* 09.09.2003	Priority date *(day/month/year)* 27.09.2002
International Patent Classification (IPC) or both national classification and IPC G01N33/68		
Applicant JANSSEN PHARMACEUTICA N.V. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
25.03.2004	08.11.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Wagner, R Telephone No. +49 89 2399-7357

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/10092

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-25 as originally filed

Claims, Numbers

1-16 as originally filed

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☒ furnished subsequently to this Authority in written form.

   ☒ furnished subsequently to this Authority in computer readable form.

   ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 9-12

   because:

   ☒ the said international application, or the said claims Nos. 9-12 (IA) relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-16
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-16
Industrial applicability (IA)	Yes:	Claims	1-8,13-16
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item I

The claims are not numbered correctly after claim 12. The present written opinion refers to the claims as if they were numbered correctly from 1 to 16.

The sequence listing filed on 09.10.03 according to the required specifications was filed after the filing date and is therefore not considered as being part of the description (Rule 13ter.1 (f) PCT).

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claims 9-12 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement.

Reference is made to the following document:

D1: Takaomi C. Saido et al., Neuroscience Letters 215 (1996), 173-176

2. The subject-matter of claim 1 is directed to a monoclonal antibody specifically recognizing Aβ11-x peptides, which is further specified in claim 2 as recognising the sequences EVHHQ (Seq. Id. No. 1) , EVHHQKJ (Seq.Id. No. 2) in humans or related sequences in the mouse (Seq. Id. Nos 3 and 4). The monoclonal antibody is new (Article 33(2) PCT). D1 discloses on page 173, that polyclonal antibodies, which are specific for Aβ11-x can be produced by immunizing rabbits with the synthetic peptide pEVHHQK-c. The only difference between the disclosure of D1 and the present antibodies lies in the fact that the present antibody is monoclonal. As the methods for producing monoclonal antibodies are well-known in the art, the

subject-matter of claims 1 and 2 does not involve an inventive step (Article 33(3) PCT). The additional features of dependent claims 3, 4 relating to the labeling of antibodies, of dependent claim 5 relating to the immobilisation on a carrier are well-known in the field and do not confer an inventive step on the antibody. Dependent claim 6 specifies two antibodies which are expressed by deposited hybridoma cell lines. The additional feature of being expressed by a defined hybridoma cell line does not confer an inventive step (Article 33(3) PCT) on the antibody of claim 6. The hybridomas (claim 7) producing the non-inventive antibodies do not involve an inventive step either.

3. The methods for detecting Aβ11-x using the non-inventive antibodies (claims 8-13) and the kit and composition comprising said antibodies (claims15, 16) do not appear to involve an inventive step (Article 33(3) PCT).

4. Regarding claim 12 the application has not disclosed any data supporting the alleged technical effect (i.e.the diagnosis of a beta-amyloid related disease) on which the evaluaton of the presence or absence of an inventive step could be based. Therefore the subject-matter of claim 14 cannot be considered to involve an inventive step (Article 33(3) PCT).

FURTHER REMARKS:

For the assessment of the present claims 9-12 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO does not not recognize as industrially applicable methods comprising a surgical step.